



**CREIGHTON
UNIVERSITY**
Department of Surgery

Reginald Q. Knight, M.D.
Chief, Division of Orthopaedics
Associate Professor

Steven G. Kumagai, M.D.
Instructor

December 2, 1999

Documentation Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

RE: Docket # 97N-484S

Dear Ladies and Gentlemen:

It has been brought to my attention that the FDA will formulate regulations regarding the use of Allograft bone. These regulations may adversely impact my ability to treat patients requiring Allograft tissues. Thus far, I have had an extensive practice in spine surgery that has benefited from the use of Allograft material. Please take in the consideration the fact that formal FDA approval does place a significant financial burden upon the tissue banks and this would then preclude the use of these tissues in many instances. This preclusion would have an adverse effect on the quality of care provided to my patients.

If you have any questions regarding my opinion, please feel free to contact me.'

Sincerely yours,

Reginald Q. Knight, M.D.
Chief, Division of Orthopaedics
Associate Professor, Creighton University

97N-484S

C94

**CREIGHTON
UNIVERSITY**



School of Medicine

Division of Orthopaedic Surgery
601 North 30th Street
Omaha, Nebraska 68131

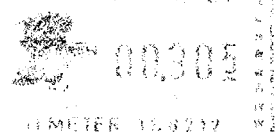
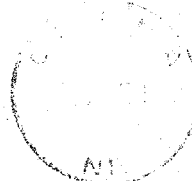
CREIGHTON
UNIVERSITY

7-21-89
U.S. NEWS

"Don't Call go"

#

1



Documentation Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

